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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,599	04/12/2004	Thomas R. Keyer	8932-927-999	3549
51832 7590 02/21/2007 JONES DAY 222 EAST 41ST STREET NEW YORK, NY 10017-6702			EXAMINER SHAFFER, RICHARD R	
			ART UNIT	PAPER NUMBER
			3733	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/21/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/822,599

Applicant(s)

KEYER ET AL.

Examiner

Richard R. Shaffer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-51 and 55-76 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 51 and 55-76 is/are allowed.
- 6) ☒ Claim(s) 1-13, 15-18, 21-37, 39-42 and 45-50 is/are rejected.
- 7) ☒ Claim(s) 14, 19, 20, 38, 43 and 44 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

The amendments to the claims filed on November 20<sup>th</sup>, 2006 are acknowledged and accepted by the examiner. The corresponding rejections under 35 U.S.C. 112, second paragraph are hereby withdrawn.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-12, 15-17, 21-23, 27-36, 39-41, and 45-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Markworth et al (US Patent 6,660,006).

Markworth et al disclose a system (**Figure 6B**) comprising: a holder assembly (**200**) having a plurality of fingers (**206**) pointing radially inward at a distal end for engaging a spinal implant body (**104**); a release assembly (**300 and 400**) made of a pusher member (**400**) and a tubular member (**300**); the tubular member slidably disposed (partially) within the holder assembly (**200**); the pusher member (**400**) sized to slidably surround (coaxially accept) a portion of the holder assembly (**200**); the pusher (**400**) having a recess at the left most portion of **404** for engaging a longitudinal spinal

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rod (114); the fingers (206) define a U-shaped recess configured to correspond with the recess formed in the pusher member to allow the spinal rod to extend completely through the holder assembly and pusher member; the fingers (206) engage recesses (105) of the spinal implant; an actuating system with a first grip (514), second grip (218), a first jaw member (one of many 704), and a second jaw member (another one of many 704); the distal end of the tubular member (300) includes a hole (308) to correspond with a hole (412) on the pusher in order to receive a pin (112); the tubular member (300) also being sized to accept the spinal implant body (104) within; the proximal end of the holder assembly (200) has a slot (222) to accept a portion of the actuating member; the tubular member (300) having a pair of slots (306 – on both sides) to also receive a portion of the actuating member, the slots facilitate proper alignment of the tubular member within the holder assembly; the first grip member (514) is pivotally coupled to the first jaw member (704); the second grip member (218) is pivotally coupled to the second jaw member (another 704); the spinal implant having a fastener (120); a cylindrical body (104); and an anchor member (unlabeled) with a curvate head (inherent when considering **Figure 1D** with **Figure 1E**) that fits within the cylindrical body.

Claims 1, 11, 16-18, 27, 35-37, and 40-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Beale et al (US Patent 6,440,133).

Beale et al disclose a device comprising:

**[First Interpretation]** a holder assembly (100); a release assembly (80 and 500); an actuating member (52, 54, 130, 140, 120, and 122); the release assembly

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comprising a tubular member (80) disposed within holder (100) and a pusher member (500) disposed about (Column 7, Lines 1-37) holder (100); a proximal end of the holder assembly (100) has a slot (110a) to receive a portion of the actuating member; the tubular member (80) has a pair of slots (91) to correspond with a pair of slots (114) in the holder assembly (100); the actuating member has a first hand grip (54), a second hand grip (52), a first jaw member (130), and a second jaw member (140); the first grip (54) and first jaw (130) are pivotally coupled; the second grip (52) and second jaw (140) are also pivotally coupled; pins (139, 149) connect the first grip (54) to the second jaw (140) member and the second grip (52) to the first jaw member (130).

**[Second Interpretation]** a holder assembly (80) having a pair of fingers (94, 96) having inward pointing ledges (94f, 94e, 96f, 96c); a release assembly (100); an actuating assembly (52, 54, 130, 140, 120, and 122); the proximal end of the holder assembly (80) having a slot (98a) to connect with a portion of the actuating member; the release assembly (100) having a proximal pair of slots (118, 119) to connect with a portion of the actuating member; the actuating member has a first hand grip (54), a second hand grip (52), a first jaw member (130), and a second jaw member (140); the first grip (54) and first jaw (130) are pivotally coupled; the second grip (52) and second jaw (140) are also pivotally coupled; pins (139, 149) connect the first grip (54) to the second jaw (140) member and the second grip (52) to the first jaw member (130).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24-26 and 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Markworth et al in view of Errico et al (US Patent 5,688,274).

Markworth et al disclose all of the claimed limitations except for a spinal implant with an external collar to compress the spinal implant body about the head of the bone anchor. Errico et al teach (**Column 5, Lines 1-65, Figure 21**) a bone anchor using a polyaxial head enclosed by a compressible body (**208**) and locked by a collar (**250**). The benefit of such an arrangement is to allow for ease of surgery. It allows the surgeon to easily implant components with minimal concern that improper alignment will occur. First the bone anchor can be placed in the subject, then the body member placed atop the bone anchor. Then a spinal rod placed within cavity (**224**) and the entire device repositioned until the desired alignment is achieved and finally fixed in place. It would have been obvious as a matter of design choice to one having ordinary skill in the art at the time the invention was made to have used a compressible body with a collar in the device of Markworth et al as a means to provide a surgeon an easily implantable yet stable spinal system.

Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beale et al.

Beale et al disclose all of the claimed limitations except for the tubular member (**80** from first interpretation) having a pair of slots configured to receive a portion of the actuating member. In **Figure 13**, an actuating portion it engages is shown having two

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slots (136b) through which the protrusion (98) passes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the tubular member (80) with two slots and the actuating portion from **Figure 13** with a protrusion since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. *In re Einstein*, 8 USPQ 167.

### ***Allowable Subject Matter***

Claims 14, 19, 20, 38, 43, and 44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 51 and 55-76 are allowed.

### ***Response to Arguments***

Applicant's arguments filed on November 20<sup>th</sup>, 2006 have been fully considered but they are not persuasive.

In regard to the prior art reference of Markworth et al, applicant argues that the slide (300) is not tubular, fits on top of the body (200) therefore not being "within," and that the actuating member does not move the holder assembly with respect to the release assembly. Applicant is given the definition from Dictionary.com Unabridged 1.1 of tubular: *having the form or shape of a tube*. The slide (300) is definitely similar to a conventional tube. It is elongated and has an opening in the center (but also opened to the side). Applicant's point of "within" is reasonable. However, applicant must be reminded that when examining a claim, the broadest reasonable interpretation is utilized. Dictionary.com also provides this definition of within: *at or to some point not*

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*beyond, as in length or distance.* The slide (300) is “within” the bounds defined by the body (200) because it does slide along the top within a fixed boundary not exceeding either side edge of body (200). Applicant’s final argument is neither persuasive nor reasonable in the slightest. The claim states “with respect to the release assembly.” Therefore, all that needs to be met is just the fact that two parts move in relation to each other. Clearly, the slide (300) and sleeve (400) move relative to one another.

In regard to the prior art reference of Beale et al, applicant first argues that extension member (500) is not attached or part of fastener engaging member (80). It is noted that the feature upon which applicant relies upon (i.e., attached or part of fastener engaging member) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further, even if it were claimed, the extension member (500) is indirectly attached to the fastener engaging member. Applicant further states that under the first interpretation, that the release assembly and holder assembly are therefore not moveable. Applicant already admits that the fastener engaging member (80) and reducing member (100) are moveable, therefore they are at least moveable relative to one another in part keeping in mind that extension member (500) is merely indirectly connected to the fastener engaging member (80) therefore allowing fastener engaging member (80) to be the portion of the release assembly to be moveable relative to the reducing member (100). Again, applicant appears confused as to what two objects being moveable with respect to (relative to) one another means.



***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Richard Shaffer  
February 12<sup>th</sup>, 2007



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